133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 1

Table of Contents

	Welcome	**1**
1	**Important Things to Know about Your Optium Xceed Diabetes Monitoring System**	**3**
	Intended Use	3
	How Your Optium Xceed Diabetes Monitoring System Works	4
	Optium Xceed Kit Contents	5
	Getting to Know Your Monitor's Features	6
2	**Setting Up Your Optium Xceed Monitor**	**9**
	Buttons to Use	9
	Setup Options	9
	How to Set the Beeper, Date, Time, & Measurement Units	11
	Set Beeper	11
	Set Time	13
	Set Date	15
	Set Time Format	18
	Set Date Format	19
	Set Blood Glucose Measurement Units	20
3	**Calibrating Your Optium Xceed Monitor**	**22**
	Why Calibrate Your Monitor?	22
	When to Calibrate Your Monitor	22
	What You Will Need	23
	How to Calibrate Your Monitor	23
	How to Recall the LOT Number or Calibration CODE	28
4	**Monitoring Your Blood Glucose**	**30**
	What You Will Need	30
	Important Information about Monitoring Your Blood Glucose	30
	How to Monitor Your Blood Glucose	31
	Understanding Your Result	39
5	**Monitoring Your Blood ß-Ketone**	**43**
	What You Will Need	43
	Important Information about Monitoring Your Blood ß-Ketone	44
	How to Monitor Your Blood ß-Ketone	45
	Understanding Your Result	52

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 2

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 3

6	**Doing A Control Solution Test**	**55**
	Why Do A Control Solution Test?	55
	When Is Doing A Control Solution Test Recommended?	55
	Important Information about Control Solution Testing	55
	What You Will Need	57
	How to Do Control Solution Testing	57
	Understanding Your Result	64
7	**Reviewing & Using Your Results**	**65**
	What Can Your Monitor Show You?	65
	How to See Results in Memory	66
	How to See Averages	69
	Transferring Your Results to A Computer	71
8	**Understanding & Troubleshooting Error Messages**	**72**
	What An Error Message Means & What You Need to Do	72
9	**Your Monitor's Specifications & Limitations**	**77**
	Important Information about Using Blood Samples from the Forearm, Upper Arm, or Base of the Thumb	80
10	**Caring For Your Monitor**	**82**
	Cleaning Your Monitor	82
	Replacing Your Monitor's Battery	83
11	**Support & Guarantee**	**87**
	References	**89**

Welcome

Thank you for choosing the Optium™ Xceed™ Diabetes Monitoring System.

Important steps for using the System are inside this guide. Please read it carefully.

Your new Optium Xceed Diabetes Monitoring System is an important tool that can help you better manage your diabetes. The System measures both blood glucose (sugar) and blood ß-Ketone. Blood glucose and blood ß-Ketone results can help you understand your diabetes and what happens with:

- Food
- Exercise
- Stress and illness
- Diabetes medications

Always monitor your blood glucose and blood ß-Ketone according to your healthcare professional's recommendations.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 5

Call Customer Service in Australia at 1800 801 478, or in New Zealand at 0800 106 100 with any questions you may have about the Optium Xceed Diabetes Monitoring System. If you cannot reach Customer Service, contact your healthcare professional.

Outside Australia and New Zealand, please contact your local Abbott Laboratories, MediSense Products office or distributor.

Please read the following items before using your Optium Xceed Diabetes Monitoring System:

- User guide
- Blood glucose electrode instructions for use
- Blood ß-Ketone electrode instructions for use
- Lancing device instructions for use and other information
- Warranty card

IMPORTANT:

Any user guide text shown in a shaded box like this one is important information. Please pay special attention to these boxes.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 6

CHAPTER 1

Important Things to Know about Your Optium Xceed Diabetes Monitoring System

Questions? Call Customer Service. See page 87.

▶Intended Use

Your Optium Xceed System:

- Is indicated for home (lay user) or professional use in the management of Patients with diabetes.
- Is for self testing or healthcare professional use outside the body (***in vitro*** diagnostic use).
- Is for monitoring glucose in fresh whole blood (for example, from the fingertip).
- Is for monitoring ß-Ketone in fresh whole blood from the fingertip.
- Measures ß-hydroxybutyrate (ß-Ketone), the most important of the three ketone bodies circulating in the bloodstream.
- Is for use ***only*** with MediSense® Optium™ Blood Glucose Electrodes and MediSense® Optium™ Ketone Blood ß-Ketone Electrodes.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 7

Healthcare professionals:

Please refer to the electrode instructions for use for more information about sample types.

Potential Infection Risk:

Healthcare professionals performing blood tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.

How Your Optium Xceed Diabetes Monitoring System Works

When you insert an electrode into your monitor, the Apply Blood message shows on your monitor's display window. When a blood sample or control solution sample is applied to the electrode, the glucose or ß-Ketone reacts with the chemicals on the electrode. This reaction produces a small electrical current that is measured. The result shows on your monitor's display window.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 8

Optium Xceed Kit Contents

Optium Xceed Monitor

Optium Xceed User's Guide – Contains system information and directions.

Carrying Case – Use this to store and carry your monitor and other monitoring supplies.

Your kit may also contain:

Optium Xceed Quick Reference Guide – Gives the basic steps to calibrate your monitor and monitor your blood glucose.

Lifetime Warranty Card – Please fill this out and return to the address provided to start your warranty. Filling out this card helps to ensure that you receive any updates regarding your Optium Xceed monitor.

Lancing Device, Lancets, Instructions for Use and Other Information

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 9

Items not included:

MediSense Control Solutions

Blood Glucose Electrodes and Instructions for Use

Blood ß-Ketone Electrodes and Instructions for Use

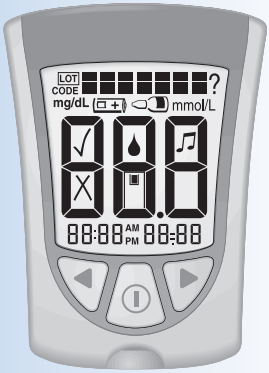
Data Management System

▶ Getting to Know Your Monitor's Features

Display Window

This shows:

- Blood glucose and blood ß-Ketone results
- Glucose LOT numbers and ß-Ketone calibration CODEs
- Previous test results and error messages
- Blood glucose averages



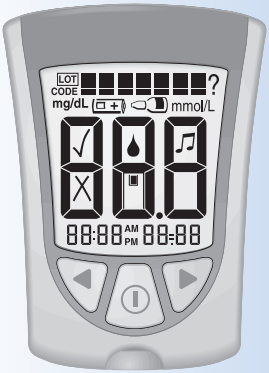
Display Check

IMPORTANT:

Each time you turn your monitor on, a full display shows. This is called a Display Check. Look at the Display Check each time it appears on your monitor's display window, especially before you monitor your blood glucose or blood ß-Ketone. The Display Check shows on the display window briefly.

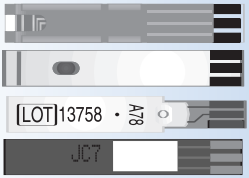
Important Information

Do not use the monitor if the monitor Display Check does not exactly match the picture here (for example, if you see a "3" instead of an "8"). The monitor may show an incorrect result when you use it. Please call Customer Service for assistance.



Electrode Port

This is where you insert:



- A blood glucose electrode
- A blood ß-Ketone electrode
- A glucose calibrator
- A ketone calibrator
- Data cable (not included) for uploading results to a computer

Mode Button

Use this button to:

- Turn monitor ON and OFF
- Access monitor setup options
- Access and save monitor settings
- Access previous results and averages

Forward Button

Back Button

Use these buttons to:

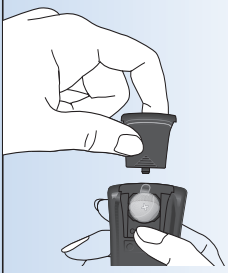
- Review and select monitor settings
- Review results and averages

Backlight Button

Use this button to:

- Turn backlight ON and OFF

Battery Compartment



This is where the battery is installed.

- If your monitor does not turn on, check that your battery is installed properly.
- For new battery installation, see Chapter 10.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 12

CHAPTER 2

Setting Up Your Optium Xceed Monitor

Questions? Call Customer Service. See page 87.

Buttons to Use

- Mode Button
- Forward Button
- Back Button

Setup Options

Set Beeper

If the beeper is set ON, it will beep when:

- The calibrator is fully inserted
- The test countdown starts
- The test countdown finishes

Set Time, Set Date

Important: Set the correct time and date before you use the monitor for the first time. This will help you keep records of when you monitor and will help you and your healthcare professional make informed decisions about your care. **You must set the time and date to review averages**.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 13

You may need to re-set the time and date:

- After you replace the battery.
- When you travel between time zones or when the time zone you are in changes.

In "Set Date", you set the year, month, and day.

Set Time Format

In "Set Time Format", you choose how the time shows on the monitor's display window.

Set Date Format

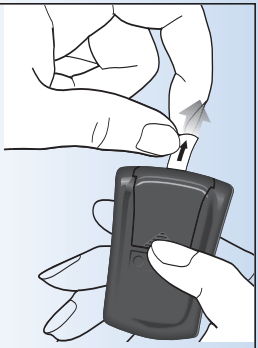
In "Set Date Format", you choose how the month and day show on the monitor's display window.

Set Measurement Units

Consult your healthcare professional before changing the blood glucose measurement units. Blood glucose measurement units are in mg/dL or mmol/L.

Blood ß-Ketone measurement units are in mmol/L only.

How to Set the Beeper, Date, Time, & Measurement Units



To begin, pull the battery tab out. Your monitor should be turned OFF. You will automatically be prompted to set the time and date the first time you press the mode button to turn your monitor on (see Set Time and Set Date sections in this chapter).

Before you start, please note: "Press and Hold" means that you press the button in for at least 2 seconds. "Press and Release" means that you press the button and let it go quickly.

Press and Hold the ⓘ button to turn the monitor off and save your settings at any time. The monitor automatically turns off after 30 seconds of no action.

If you like the setting that you see on your monitor and do not want to change it, Press and Release the ⓘ button to move to the next setup option.

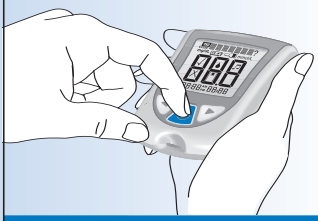
Beeper ON

Beeper OFF

Set Beeper

The √ means the beeper is ON.

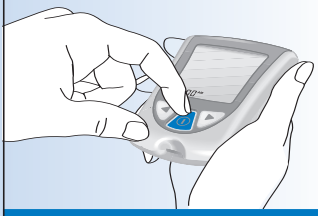
The X means the beeper is OFF.



1 To turn your monitor ON, Press and Hold the ⓘ button.

The beeper ON message shows on the display window. The musical notes flash on and off, and the monitor beeps.

2 To change the beeper setting, Press and Release the ◀ button or the ▶ button once.



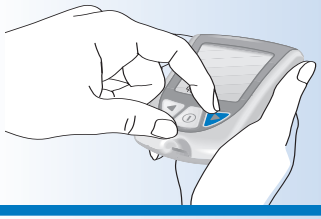
3 Press and Release the ⓘ button to save the beeper setting and to move to Set Time (Hour).

Set Time

Hour:

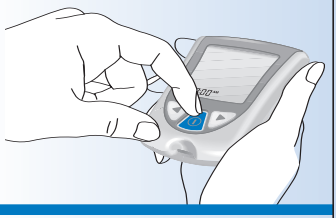
The Hour flashes on and off.

1 Press and Release the ▶ button to move the hour forward.



2 If you go past the correct hour, Press and Release the ◀ button to move the hour back.

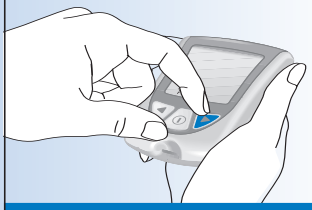
3 Press and Release the ⓘ button to save the hour and to move to Set Minutes.



133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 17

Minutes:

The Minutes flash on and off.



1 Press and Release the ▶ button to move the minutes forward.

2 If you go past the correct minute, Press and Release the ◀ button to move the minutes back.

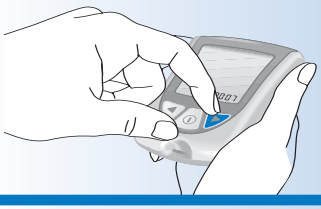
3 Press and Release the ⓘ button to save the minutes and to move to Set Date.

Set Date

Year:

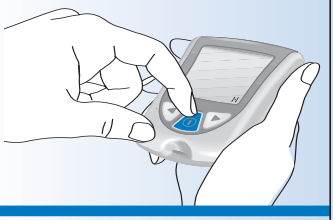
The Year flashes on and off.

1 Press and Release the ▶ button to move the year forward.



2 If you go past the correct year, Press and Release the ◀ button to move the year back.

3 Press and Release the ⓘ button to save the year and to move to Set Month.



Month:

The Month flashes on and off.

1 Press and Release the ▶ button to move the month forward.

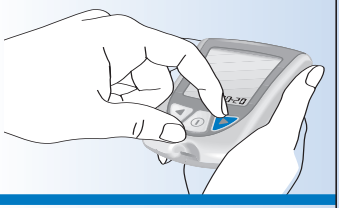
2 If you go past the correct month, Press and Release the ◀ button to move the month back.

3 Press and Release the ⓘ button to save the month and to move to Set Day.

Day:

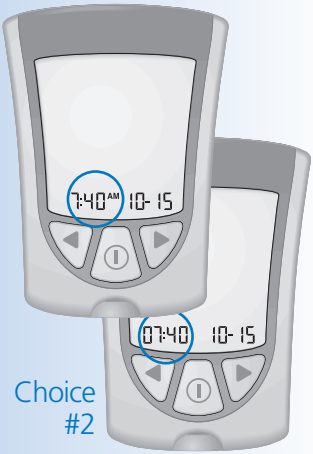
The Day flashes on and off.

1 Press and Release the ▶ button to move the day forward.



2 If you go past the correct day, Press and Release the ◀ button to move the day back.

3 Press and Release the ⓘ button to save the day and to move to Set Time Format.



Set Time Format

You have two choices:

Choice #1: For the 12-hour format, AM or PM shows.

Choice #2: For the 24-hour format, AM or PM does not show.

1 To change the Time Format, Press and Release the ◀ button or the ▶ button once.

2 Press and Release the ⓘ button to save the Time Format and to move to Set Date Format.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 22

Set Date Format

You have two choices:

Choice #1: For the month-day format, "▬" shows with the date.

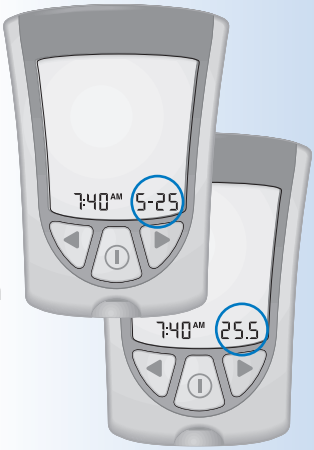
Example:

"May 25" shows as "5-25".

Choice #2: For the day.month format, "●" shows with the date.

Example:

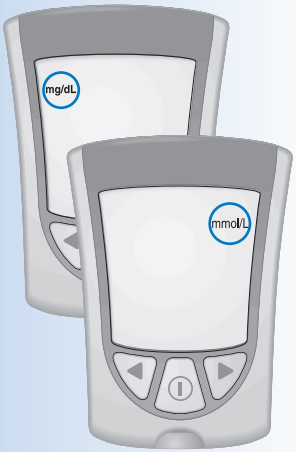
"25 May" shows as "25.5".



1 To change the Date Format, Press and Release the ◀ button or the ▶ button once.

2 Press and Release the ⏻ button to save the Date Format and to move to Set Measurement Units.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 23



Set Blood Glucose Measurement Units

Consult your healthcare professional before changing the blood glucose measurement units.

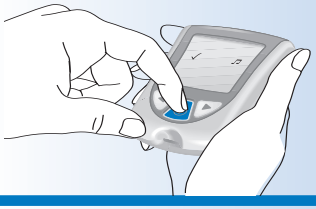
For mg/dL or mmol/L:

The mg/dL measurement units flash on and off in the upper left corner of the display window.

The mmol/L measurement units flash on and off in the upper right corner of the display window.

1 To change the measurement units, Press and Release the ◀ button or the ▶ button once.

2 Press and Release the ⏻ button to save the measurement units and to return to Set Beeper.



Press and Hold the ⏻ button to turn your monitor off.

You have successfully set up your monitor.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 25

CHAPTER 3

Calibrating Your Optium Xceed Monitor

Questions? Call Customer Service. See page 87.

Why Calibrate Your Monitor?

Your Optium Xceed monitor must be calibrated so that it can recognize the electrode you are using. Calibration ensures that your results are accurate.

When to Calibrate Your Monitor

- When you use the monitor for the first time.
- **EACH** time you open and use a new box of blood glucose or blood ß-Ketone electrodes.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 26

What You Will Need

- Optium Xceed monitor
- For glucose calibration:
  - Blood glucose electrode
  - Blood glucose electrode instructions for use
  - Blood glucose electrode calibrator
- For ß-Ketone calibration:
  - Blood ß-Ketone electrode
  - Blood ß-Ketone electrode instructions for use
  - Blood ß-Ketone electrode calibrator

How to Calibrate Your Monitor

When you insert an electrode for the first time, the display window shows:

This means the monitor is **not** calibrated for blood glucose monitoring.

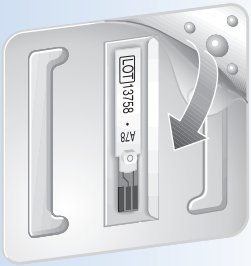
This means the monitor is **not** calibrated for blood ß-Ketone monitoring.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 27

IMPORTANT:

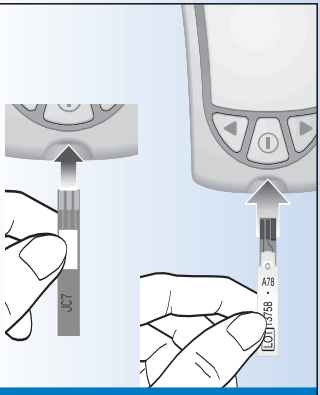
- Use only the calibrator that is packaged in the box of electrodes you are using.
- **Do not** use electrodes that have expired. Check the expiration date on the electrode foil packet and electrode box. If only the year and month are shown, the expiration date is the last day of the month.

1 Remove the glucose or ß-Ketone calibrator package from the new box of electrodes.



2 Open the calibrator package. Find the three raised bumps on the calibrator package. Peel the clear cover away from the three raised bumps.

3 Hold the calibrator with the LOT number (glucose) or calibration CODE (ß-Ketone) facing you.



4 Insert the calibrator into the electrode port. Push it in until it stops.

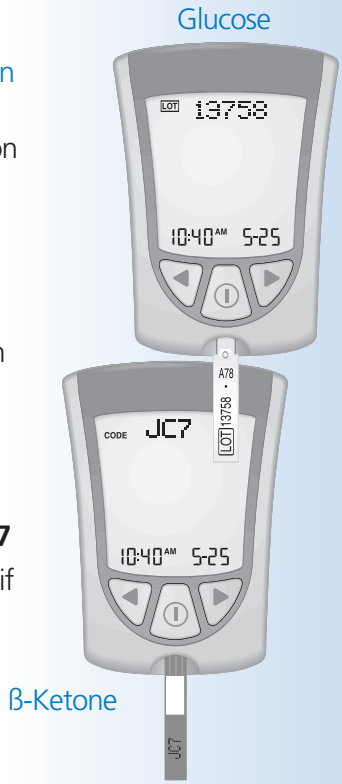
The Display Check shows on the display window, followed by the time, month, and day.

Next, the LOT number (glucose) or calibration CODE (ß-Ketone) shows on the display window.

a. Example of glucose LOT number: **LOT 13758**

b. Example of ß-Ketone calibration CODE: **CODE JC7**

Then you hear the beeper, if the beeper is ON.



133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 29

5 Check that the LOT number or calibration CODE on all these items matches:

✓ Display window

✓ Electrode calibrator

✓ Electrode instructions for use

✓ Electrode foil packet

When the LOT number or calibration CODE on all these items matches:

What It Means:

Calibration is complete.

What to Do:

You may now monitor your blood glucose or blood ß-Ketone.

When the LOT number or calibration CODE on all these items DOES NOT match:

What It Means:

Your monitor may not be calibrated for the box of electrodes you are using.

What to Do:

- Check that you are using the calibrator that came in the box of electrodes you are using.
- Try to calibrate again.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 30

IMPORTANT: If the LOT number or calibration CODE still does not match, contact Customer Service. **Do not** attempt to monitor your blood glucose or blood ß-Ketone. Your monitor may show an incorrect result.

6 Remove the calibrator from the monitor and store it in your monitor's carrying case.

IMPORTANT: Do not throw the calibrator away until you have used all of the electrodes in the box.

If you have any trouble calibrating your system, please contact Customer Service.

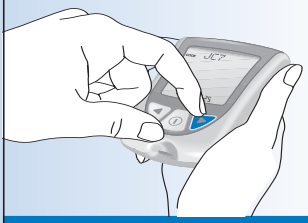
133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 31

▶How to Recall the LOT Number or Calibration CODE

1 To recall the glucose LOT number, Press and Hold the ▶ button. While holding the ▶ button, Press and Hold the ⓘ button.

The Display Check shows on the display window, then the glucose LOT number shows with the time, month, and day of the most recent glucose calibration.

2 After the glucose LOT number is displayed, you can recall the ß-Ketone calibration CODE. Press and Release the ▶ button or the ◀ button.



The ß-Ketone calibration CODE shows with the time, month, and day of the most recent ß-Ketone calibration.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 32

Note: If the LOT number or calibration CODE that shows on your monitor's display window is not correct:

What It Means:

Your monitor may not be calibrated for the box of electrodes you are using.

What To Do:

- Re-calibrate your monitor.
- Check that you are using the calibrator that came in the box of electrodes you are using.

Remember, improper calibration will cause incorrect results.

3 Press and Hold the ⏻ button to turn your monitor off.

CHAPTER 4

Monitoring Your Blood Glucose

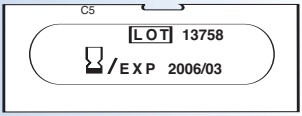
Questions? Call Customer Service. See page 87.

What You Will Need

- Blood glucose electrode with its instructions for use
- Optium Xceed monitor calibrated to match the LOT number of the blood glucose electrode you are using
- Lancing device and a new, sterile lancet

Important Information about Monitoring Your Blood Glucose

- **Do not** use out-of-date electrodes. Check the expiration date printed on the electrode box and on each electrode foil packet. If only the month and year are printed on the electrode, then the expiration date is the last day of that month.
- For more detailed information about your electrode, please read its instructions for use before monitoring.
- Use the electrode **immediately** when you take it out of its foil packet.



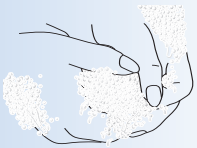
Example:
Expiration date
March 31, 2006

- **Do not** use a wet, bent, scratched, or damaged electrode.
- **Do not** use the electrode if its foil packet has a puncture or tear in it.
- Before you monitor, allow your monitor and electrode to reach the recommended operating range of the electrode. The electrode operating range is in the "Limitations of Procedure" section of your blood glucose electrode instructions for use.
- Read the lancing device instructions for use.

▶How to Monitor Your Blood Glucose

Getting Started

1 Prepare your lancing device.



2 Wash your hands using warm soapy water and dry them completely.

3 Remove the electrode from its foil packet.

Note: For pictures that show how to open the blood glucose electrode foil packet, please see the information card in the box of blood glucose electrodes.

4 Insert the three black lines at the end of the electrode into the electrode port.

5 Push the electrode in until it stops.

The monitor turns on automatically.

These items show on the display window, one after the other:

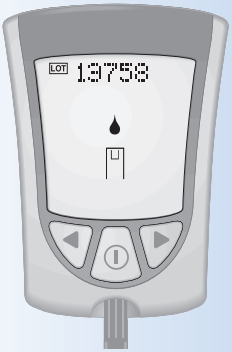
- Display Check – Remember to make sure that all items in the picture here show on the display window. (See Chapter 1 for more information about the Display Check.)

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 36

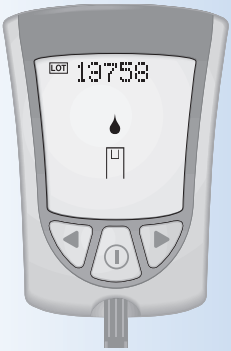
- Time, month, and day (if set)

  If date and time are not set, dashes will show instead of numbers.

- LOT number for the box of blood glucose electrodes you are using.

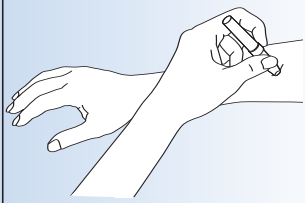


- Apply Blood message, which tells you that the monitor is ready for you to apply blood to the blood glucose electrode.

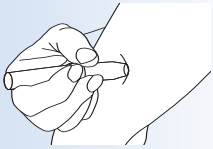


133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 37

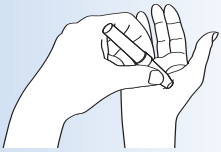
Fingertip sampling



Forearm sampling



Upper arm sampling



Base of thumb sampling

Obtaining A Blood Drop

Use your lancing device to obtain a blood drop.

Recommendations for Obtaining a Blood Drop

- To obtain a sample from an alternative site (forearm, upper arm, or base of the thumb), use an appropriate alternative site lancing device.
- Before you obtain a blood sample from the fingertip, forearm, upper arm, or base of the thumb, make sure the sample site is clean, dry, and warm. To warm the sample site, wash it in warm water, rub the skin vigorously for a few seconds, or apply a warm pad to it.
- Hang your arm down before pricking your finger or the base of the thumb to help blood flow.
- To obtain a blood sample from the arm, use a fleshy area away from bone. Avoid areas where there is a lot of hair.
- Avoid squeezing the puncture site.
- Apply the blood sample to the electrode immediately.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 38

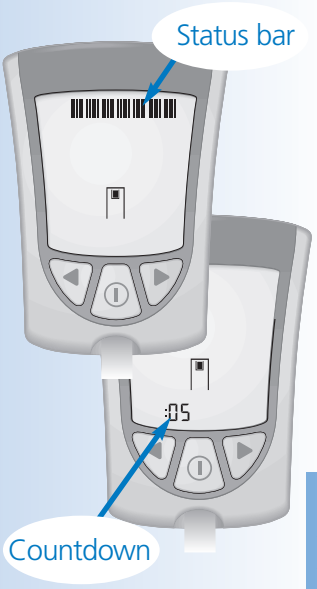
Lancets and Lancing Device

- Lancets are for one-time use only. Use a new lancet each time you monitor.
- Discard your used lancet properly. Put it in an empty puncture-resistant container, such as a plastic milk carton or detergent bottle.
- Never share your lancing device or lancet with another person.

Applying the Blood Drop to the Electrode

1 Touch the blood drop to the white area at the end of the electrode. The blood is drawn into the electrode.

Note: If the monitor shuts off before you apply blood to the electrode, remove the electrode from the monitor and try again.



2 Continue to touch the blood drop to the end of the electrode until the monitor begins the test. The monitor begins the test when:

- You hear the beeper, if the beeper is ON.
- The display window shows the status bar.
- Then the display window shows the countdown.

Note: Do not remove the electrode from the monitor or disturb it during the countdown.

Important: If the countdown does not start:

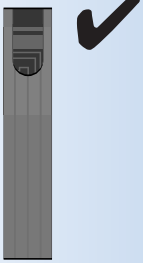
What It Means:

You might not have applied enough blood to the electrode.

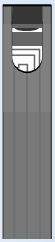
What to Do:

- Apply a second drop of blood to the electrode within 30 seconds of the first drop.
- If the countdown still does not start or if more than 30 seconds have passed, discard the electrode, turn off your monitor, and try again with a new electrode.

Correct



Apply second drop



3 At the end of the countdown:

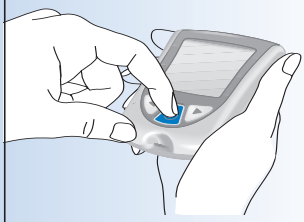
- If the beeper is ON, listen for the beeper.
- The blood glucose result shows on the display window.
- The result is stored in your monitor's memory. You may also write the result in your logbook.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 41

Shutting Off Your Monitor

1 Removing the electrode from the electrode port turns off the monitor. You can use the opened foil packet to remove and discard your used electrode.

2 Discard the electrode properly.



Note: You may also turn the monitor off by Pressing and Holding the ⏻ button. If you do not turn your monitor off or pull the electrode out, the monitor shuts off automatically after 60 seconds.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 42

▶Understanding Your Result

"LO" Result

What It Means:

Your monitor has determined that your blood glucose result is lower than 1.1 mmol/L (20 mg/dL) or there may be a problem with the electrode.

What to Do:

Monitor your blood glucose again with a new electrode. If **LO** shows on the display window again, contact your healthcare professional **immediately**.

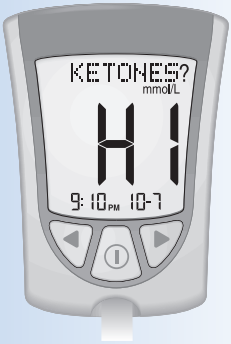
Result 16.7 mmol/L or Higher

When your blood glucose result is 16.7 mmol/L (300 mg/dL) or higher, **KETONES?** flashes on and off on the display window.

What to Do:

If you check your ketones as part of your diabetes management program, it is recommended that you check your blood ß-Ketone.

"HI" Result



What It Means:

Your monitor has determined that your blood glucose result is higher than 27.8 mmol/L (500 mg/dL) or there may be a problem with the electrode.

What to Do:

Monitor your blood glucose again with a new electrode. If **HI** shows on the display window again, contact your healthcare professional **immediately**.

If you check your ketones as part of your diabetes management program, it is recommended that you check your blood ß-Ketone.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 44

"E-4" Result

What It Means:

Your blood glucose may be too high to be read by the system, or there may be a problem with the electrode.

What to Do:

Monitor your blood glucose again with a new electrode. If **E-4** shows on the display window again, contact your healthcare professional **immediately**.

Important:
It is recommended that you repeat the blood glucose test with a new electrode when:

- **LO** shows on the display window.
- You obtain a low blood glucose result, but you do not have symptoms of low blood glucose.
- Your monitor displays a blood glucose result that is unusually low, lower than 2.8 mmol/L (50 mg/dL).

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 45

- **HI** shows on the display window.
- You obtain a high blood glucose result, but you do not have symptoms of high blood glucose.
- Your monitor displays a result that is unusually high, higher than 16.7 mmol/L (300 mg/dL).
- You question your result.

Important:

A result that is incorrect may have a serious medical outcome. Consult your healthcare professional before changing your diabetes medication program.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 46

CHAPTER 5

Monitoring Your Blood ß-Ketone

Questions? Call Customer Service. See page 87.

It is important to check your ketones when:

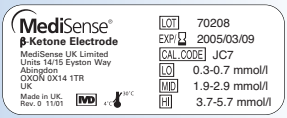
- You have an illness.
- Your blood glucose is higher than 16.7 mmol/L (300 mg/dL).
- You are experiencing unusual blood glucose results.
- You and your healthcare professional determine that it is necessary.

▶ What You Will Need

- Blood ß-Ketone electrode with its instructions for use
- Optium Xceed monitor calibrated to match the calibration CODE of the blood ß-Ketone electrode you are using
- Lancing device and a new, sterile lancet

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 47

Important Information about Monitoring Your Blood ß-Ketone



Example:
Expiration date
March 9, 2005

- For more detailed information about your blood ß-Ketone electrode, please refer to its instructions for use before monitoring.
- **Do not** use out-of-date electrodes. Check the expiration date printed on the electrode box and on each electrode foil packet.
- **Do not** put urine on the blood ß-Ketone electrode.
- Use the electrode immediately when you take it out of its foil packet.
- **Do not** use a wet, bent, scratched, or damaged electrode.
- **Do not** use the electrode if its foil packet has a puncture or tear in it.
- Use each electrode only once.
- Before you monitor, allow your monitor and electrode to reach the recommended operating range of the electrode. The electrode operating range is in the "Limitations of Procedure" section of your blood ß-Ketone electrode instructions for use.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 48

- Read the lancing device instructions for use.
- The blood ß-Ketone electrode foil packet contains a desiccant tablet (Zeolite - Sodium Calcium Aluminosilicate). Although this material is not considered dangerous[1], the following safety advice should be observed:

1. Keep away from children.
2. Do not expose to water as product gets hot and could cause burns.
3. Do not eat, and avoid contact with eyes and skin. May cause burns to the mouth and throat.
4. If swallowed, drink two glasses of water. Seek medical help.

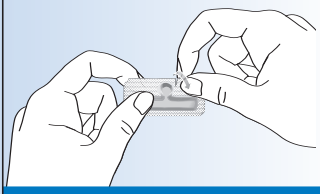
▶ How to Monitor Your Blood ß-Ketone

Getting Started

1 Prepare your lancing device.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 49

2 Wash your hands using warm soapy water and dry them completely.



3 Remove the electrode from its foil packet.

4 Insert the three black lines at the end of the electrode into the electrode port.

5 Push the electrode in until it stops.

The monitor turns on automatically.

These items show on the display window, one after the other:

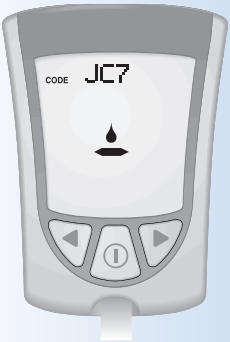
- Display Check – Remember to make sure that all items in the picture here show on the display window. (See Chapter 1 for more information about the Display Check.)

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 50

- Time, month, and day (if set)

  If date and time are not set, dashes will show instead of numbers.

- Calibration CODE for the box of blood ß-Ketone electrodes you are using.



- **KETONE** and Apply Blood message, which tell you that the monitor is ready for you to apply blood to the blood ß-Ketone electrode.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 51

Obtaining A Blood Drop

Use your lancing device to obtain a blood drop.

Fingertip sampling

Important: Blood ß-Ketone electrodes have not been evaluated for alternative site monitoring. **Use only fingertip blood samples for blood ß-Ketone monitoring.**

Recommendations for Obtaining A Blood Drop

- Before you obtain a blood sample from the fingertip, make sure the sample site is clean, dry, and warm. To warm the sample site, wash it in warm water or rub the skin vigorously for a few seconds.
- Hang your arm down before pricking your fingertip to help blood flow.
- Avoid squeezing the fingertip.
- Apply the blood sample to the electrode immediately.

Lancets and Lancing Device

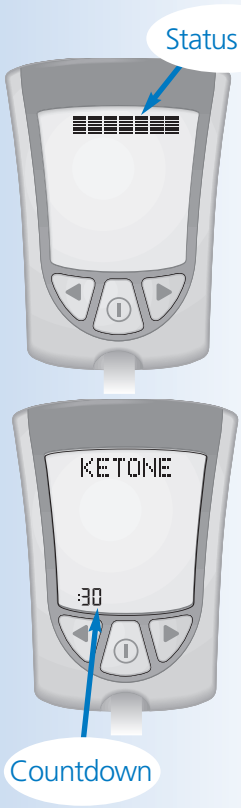
- Lancets are for one-time use only. Use a new lancet each time you monitor.
- Discard your used lancet properly. Put it in an empty puncture-resistant container, such as a plastic milk carton or detergent bottle.
- Never share your lancing device or lancet with another person.

Applying the Blood Drop to the Electrode

1 Touch the blood drop to the purple area on the top of the electrode. The blood is drawn into the electrode.

Note: If the monitor shuts off before you apply blood to the electrode, remove the electrode from the monitor and try again.

2 Continue to touch the blood drop to the purple area on the top of the electrode until the monitor begins the test. The monitor begins the test when:



- You hear the beeper, if the beeper is ON.
- The display window shows the status bar.
- Then the display window shows the countdown.

Note: Do not remove the electrode from the monitor or disturb it during the countdown.

Important: If the countdown does not start:

What It Means:

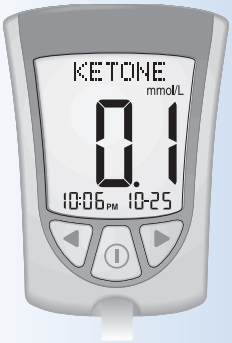
You might not have applied enough blood to the electrode.

What to Do:

- Apply a second drop of blood to the electrode within 30 seconds of the first drop.
- If the countdown still does not start or if more than 30 seconds have passed, discard the electrode, turn off your monitor, and try again with a new electrode.

3 At the end of the countdown:

- If the beeper is ON, listen for the beeper.
- The blood ß-Ketone result shows on the display window with the word **KETONE**.
- The result is stored in your monitor's memory as a blood ß-Ketone result.

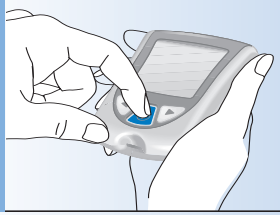


Shutting Off Your Monitor

1 Removing the electrode from the electrode port turns off the monitor. You can use the opened foil packet to remove and discard your used electrode.

2 Discard the electrode properly.

Note: You may also turn the monitor off by Pressing and Holding the ⏻ button. If you do not turn your monitor off or pull the electrode out, the monitor shuts off automatically after 60 seconds.



133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 55

Understanding Your Result

Blood ß-Ketone is expected to be lower than 0.6 mmol/L.[3] Blood ß-Ketone may be higher when a person is ill, is fasting, exercises vigorously, or if blood glucose levels are not controlled.[2-4]

When:

- Blood ß-Ketone result is between 0.6 and 1.5 mmol/L and blood glucose result is 16.7 mmol/L (300 mg/dL) or higher:

What It Means:

A problem requiring medical assistance may be occurring.

What to Do:

Contact your healthcare professional. Follow his or her instructions for sick day management.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 56

When:

- Blood ß-Ketone result remains high or becomes higher than 1.5 mmol/L:

What It Means:

You may be at risk of developing diabetic ketoacidosis (DKA).[3-7]

What to Do:

Contact your healthcare professional **immediately**.

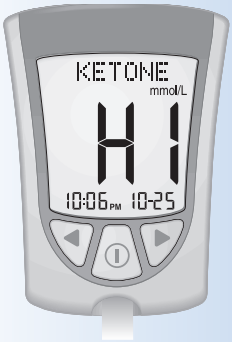
"HI" Result

What It Means:

Your monitor has determined that your blood ß-Ketone result is higher than 6.0 mmol/L, or there may be a problem with the electrode.

What to Do:

Monitor your blood ß-Ketone again with a new electrode. If **HI** shows on the display window again, contact your healthcare professional **immediately**.



"E-4" Result

What It Means:

There may be a problem with the electrode.

What to Do:

Monitor your blood ß-Ketone again with a new electrode. If **E-4** shows on the display window again, contact your healthcare professional **immediately**.

Important: It is recommended that you repeat the blood ß-Ketone test with a new electrode when:

- **HI** appears in the display window.
- Your result is unusually high.
- You question your result.
- You obtain a 0.0 mmol/L blood ß-Ketone result BUT your blood glucose is higher than 16.7 mmol/L (300 mg/dL).

Important: A result that is incorrect may have a serious medical outcome. Consult your healthcare professional before changing your diabetes medication program.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 58

CHAPTER 6

Doing A Control Solution Test

Questions? Call Customer Service. See page 87.

▶Why Do A Control Solution Test?

The control solution test tells you that your monitor and electrodes are working correctly. A control solution test is similar to when you monitor your blood glucose or blood ß-Ketone, except you use a MediSense Control Solution. **You do not use a drop of blood in a control solution test.**

▶When Is Doing A Control Solution Test Recommended?

- With each new electrode LOT number
- When you question your results
- To make sure that your monitor and electrodes are working properly

▶Important Information about Control Solution Testing

- For more detailed information about control

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 59

solutions, read the control solution instructions for use.

- MediSense Control Solutions may be used for glucose or ketone control solution testing.
- **Do not** use the control solution if the expiration date has passed. Check the expiration date printed on the control solution bottle.
- When you open a control solution bottle for the first time, count forward 90 days and write this date on the control solution bottle using a pen that won't smear or wipe off. Throw away any remaining solution after this date.
- The results obtained from control testing do not reflect your personal blood glucose or blood ß-Ketone levels in any way.
- **Do not** swallow the control solution.
- **Do not** inject the control solution or use the control solution as eye drops.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 60

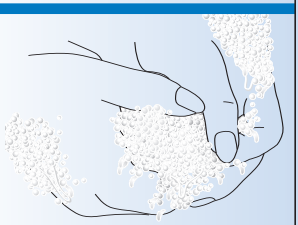
What You Will Need

- Optium Xceed monitor calibrated to match the LOT number (glucose) or calibration CODE (ß-Ketone) of the electrode you are using
- Blood glucose or blood ß-Ketone electrode and its instructions for use
- MediSense Control Solutions and instructions for use

How to Do Control Solution Testing

Getting Started

1 Wash your hands using warm soapy water and dry them completely.



133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 61

2 Remove the electrode from its foil packet.

Note: For pictures that show how to open the blood glucose electrode foil packet, please see the information card in the box of blood glucose electrodes.

3 Insert the three black lines at the end of the electrode into the electrode port.

4 Push the electrode in until it stops.

The monitor turns on automatically.

These items show on the display window, one after the other:

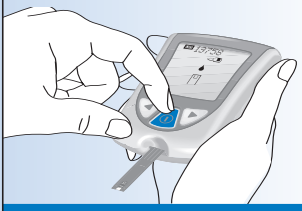
- Display Check – Remember to make sure that all items in the picture here show on the display window. (See Chapter 1 for more information about the Display Check.)

- Time, month, and day (if set)

  If date and time are not set, dashes will show instead of numbers.

- LOT number (glucose) or calibration CODE (ß-Ketone) for the box of electrodes you are using.
- Apply Blood message, which tells you that the monitor is ready for you to apply control solution to the electrode.

Note: If you are a doing a ß-Ketone control solution test, **KETONE** will show on the monitor's display window with the ß-Ketone Apply Blood message.



5 To mark the test as a control test, Press and Release the ⏻ button once. ☜ shows on the display window.

Important: If you do not mark the test as a control test, it will be saved in your monitor's memory as one of your personal blood glucose or blood ß-Ketone results. This could affect your blood glucose averages.

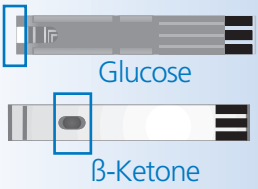
133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 64

Applying Control Solution to the Electrode

1 Turn the control solution bottle upside down three to four times to mix the solution.

2 Remove the cap.

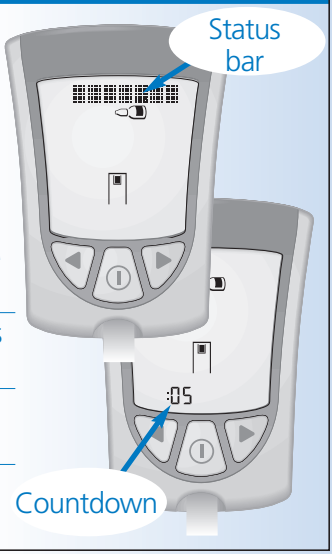
3 Apply a drop of control solution to the electrode in the area shown here. The control solution is drawn into the electrode.



4 Continue to touch the control solution to the electrode until the monitor begins the test.

The monitor begins the test when:

- You hear the beeper, if the beeper is ON.
- The display window shows the status bar.
- Then the display window shows the countdown.



Note: Do not remove the electrode from the monitor or disturb it during the countdown.

Important: If the countdown does not start:

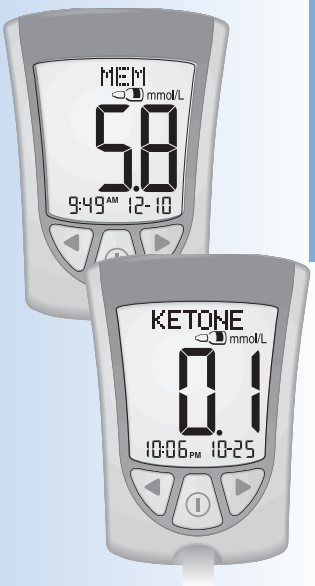
What It Means:

You might not have applied enough control solution to the electrode.

What to Do:

- Apply a second drop of control solution to the electrode within 30 seconds of the first drop.
- If the countdown still does not start or if more than 30 seconds have passed, discard the electrode, turn off your monitor, and try again with a new electrode.

Glucose



ß-Ketone

5 At the end of the countdown:

- If the beeper is ON, listen for the beeper.
- The control result shows on the display window.

Note: If you are doing a ß-Ketone control solution test, **KETONE** will also show with the result.

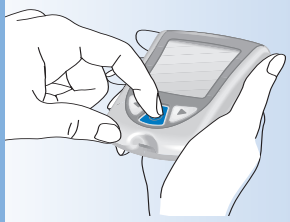
- The result is stored in your monitor's memory as a control result.

Shutting Off Your Monitor

1 Removing the electrode from the electrode port turns off the monitor. You can use the opened foil packet to remove and discard your used electrode.

2 Discard the test strip properly.

Note: You may also turn the monitor off by Pressing and Holding the ⏻ button. If you do not turn your monitor off or pull the electrode out, the monitor shuts off automatically after 60 seconds.



Understanding Your Result

Compare the control result to the "Expected Results for Use with MediSense Control Solutions" range printed on:

- The blood glucose electrode instructions for use, for glucose control solution testing.
- The blood ß-Ketone electrode instructions for use and foil packet, for ß-Ketone control solution testing.

If the control result falls within the range:

What It Means:

Your monitor and electrodes are working correctly.

If the control result **does not** fall within the range:

What It Means:

Your monitor and electrodes may not be working correctly.

What to Do:

Repeat the test with a new electrode and ensure the control solution testing instructions are followed completely. If the result is still not within the printed range, contact Customer Service.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 68

CHAPTER 7

Reviewing & Using Your Results

Questions? Call Customer Service. See page 87.

▶What Can Your Monitor Show You?

Memory

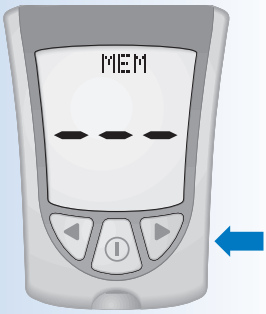
Your Optium Xceed monitor has a memory that stores up to 450 events. This is a combination of control results, your personal blood glucose and blood ß-Ketone results, and other monitor information.

You can review up to 450 of your most recent events on your monitor's display window.

Glucose Averages

You can view the average of all your blood glucose results from the last 7, 14, or 30 days. If you marked your control solution tests, the averages do not include control solution results. (For more information on marking control solution tests, see Chapter 6.)

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 69



Important:

- To review blood glucose averages, you **must** set the date and time before monitoring.
- If you **do not** mark control solution tests, this may affect your glucose averages.
- Blood glucose averages **do not** include blood ß-Ketone results, glucose control results, ß-Ketone control results, or results that do not show the time, month, and day.
- When there are no previous results or blood glucose averages to review, the display window shows three dashes.

▶How to See Results in Memory

1 Begin with your monitor turned off. Make sure there is nothing in the electrode port.

2 Press and Release the ⏻ button.

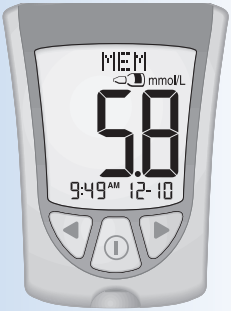
- The Display Check shows on the display window.
- Then your most recent result shows with its units on the monitor's display window, along with the time, month, and day that you got the result. (To set the correct date and time, follow the steps in Chapter 2.)

A blood glucose result in Memory will show with the letters **MEM**.

Blood Glucose result in Memory

A blood ß-Ketone result in Memory will show with the letters **KET MEM**.

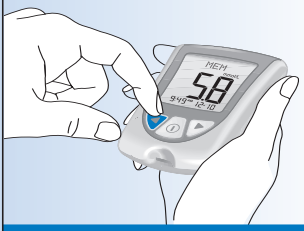
Blood ß-Ketone result in Memory



Glucose control solution result in Memory

ß-Ketone control solution result in Memory

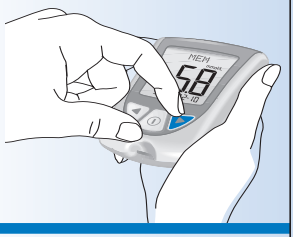
A control solution result in Memory shows with a control bottle, as long as you marked the test as a control solution test.



3 To review previous results, Press and Release the ◀ button once per result.

4 When you reach the last result in Memory, the display window shows three dashes.

5 To return to a result you previously reviewed, Press and Release the ▶ button once per result.



▶ How to See Averages

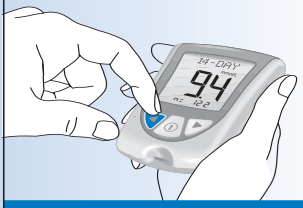
Important:

- Results that show as **LO** during blood glucose monitoring are included as 1.1 mmol/L (20 mg/dL) in blood glucose averages.
- Results that show as **HI** during blood glucose monitoring are included as 27.8 mmol/L (500 mg/dL) in blood glucose averages.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 73

1 While in Memory, Press and Release the ⓘ button at any time to see the 7-Day average of your blood glucose results.

Note: n means how many tests were performed within the 7-, 14-, or 30-Day average period.



2 Press and Release the ◀ button once to see the 14-Day average of your blood glucose results.

3 Press and Release the ◀ button again to see the 30-Day average of your blood glucose results. If you Press and Release the ◀ button again, the display window shows the 7-Day average.

4 Press and Release the ⓘ button at any time to return to Memory.

5 Press and Hold the ⏻ button to turn off your monitor. Otherwise, the monitor turns off after 30 seconds.

▶ Transferring Your Results to a Computer

The results in your Optium Xceed monitor's memory, along with the time and date of the reading, can be transferred to a computer with the use of the Precision Link® Direct Software Version 2.5 and a Precision Link communications cable (the software and cable are available for purchase separately). To install the software, please follow the instructions provided in the Precision Link User's Guide.

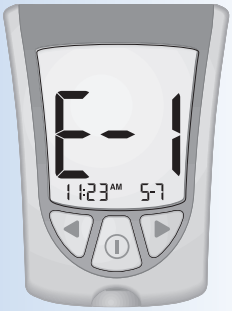
CHAPTER 8

Questions? Call Customer Service. See page 87.

Understanding & Troubleshooting Error Messages

There are times when error messages may show on your monitor's display window.

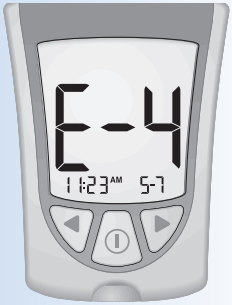
In the next few pages, we describe the error messages that may show on your monitor's display window, what they mean, and what you need to do.

Message	What It Means	What You Need to Do
	Temperature is too hot or too cold for the system to work properly.	• **Move your monitor and electrodes to a location where the temperature is appropriate and monitor again with a new electrode. You may have to wait for your monitor to adjust to the new temperature. Refer to your electrode instructions for use for the appropriate operating range.** • **If the error message appears again, contact Customer Service.**

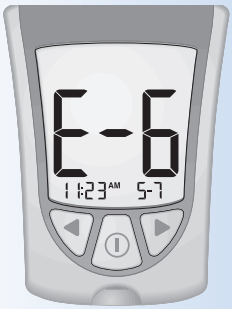
133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 76

What It Means	What You Need to Do	Message
Monitor error.	• Turn the monitor off, then repeat previous monitoring steps. • If the error message appears again, contact Customer Service.	
There may be a problem with the electrode.	• Review the monitoring instructions. • Monitor again with a new electrode. • If the error message appears again, contact Customer Service.	

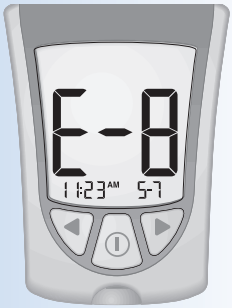
133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 77

Message	What It Means	What You Need to Do
	Blood glucose result may be too high to be read by the system. OR There may be a problem with the blood glucose or blood ß-Ketone electrode.	• **Monitor again with a new electrode.** • **If the error message appears again, contact your healthcare professional immediately.**
	Blood applied to electrode too soon.	• **Review the monitoring instructions.** • **Monitor again with a new electrode.** • **If the error message appears again, contact Customer Service.**

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 78

What It Means	What You Need to Do	Message
Calibration/ Electrode error.	• Repeat the calibration using the calibrator bar that came with the electrode you are using. • Check the date setting on your monitor. • Check the expiration date on the electrode foil packet. • If the error message appears again, contact Customer Service.	
Electrode error. Electrode is damaged, used, or the monitor does not recognize it.	• Monitor again using an electrode designed for use with Optium Xceed. • If the error message appears again, contact Customer Service.	

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 79

Message	What It Means	What You Need to Do
	Monitor error.	• Remove electrode, turn monitor off, and try to monitor again. • If the error message appears again, contact Customer Service.
	Monitor error.	• Remove electrode, turn monitor off, and try to monitor again. • If the error message appears again, contact Customer Service.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 80

CHAPTER 9

Your Monitor's Specifications & Limitations

Questions? Call Customer Service. See page 87.

Size	
Length	7.47 cm
Width	
Top	5.33 cm
Bottom	4.32 cm
Thickness	1.63 cm
Weight	42 grams
Power Source	One CR 2032 Lithium (coin cell) battery
Battery Life	Approximately 1,000 tests
Memory	Up to 450 events including control results, personal blood glucose and blood ß-Ketone results, and other monitor information.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 81

Storage Temperature

Monitor:	–25° to 55°C
Electrodes:	See electrode instructions for use.
Control Solution:	See control solution instructions for use.

Blood Glucose Assay Range

See blood glucose electrode instructions for use.

Blood ß-Ketone Assay Range

See blood ß-Ketone electrode instructions for use.

Control Solution Range

See blood glucose or blood ß-Ketone electrode instructions for use.

Functions

- Blood glucose monitoring
- Blood ß-Ketone monitoring
- Memory
- Glucose averaging: 7-Day, 14-Day, and 30-Day Averages
- Control solution marking and testing
- Backlight: If ON – Stays ON during countdown; turns OFF 30 seconds after result is displayed. If OFF – Stays OFF during countdown; stays OFF during data upload.
- Beeper: If ON – Beeps when calibrator is fully inserted and when countdown starts and finishes.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 82

Data port Yes

Monitor Operating Range

Temperature: 10° to 50°C

Relative Humidity: 10% to 90%, non-condensing

System Operating Range

Temperature: The system operating range is the operating range of the electrode you are using. See "Limitations of Procedure" section in electrode instructions for use.

Relative Humidity: 10% to 90%, non-condensing

Important Information about Using Blood Samples from the Forearm, Upper Arm, or Base of the Thumb:

- Contact your healthcare professional before you begin using any one of these alternative sites to test your blood glucose.
- Sampling from any one of these alternative sites may cause minor bruising and may leave marks that go away in a short time.
- There may be times when alternative site results are different from fingertip results. This happens when blood glucose levels change rapidly (for example, after you eat a meal, after you take insulin, or during or after exercise).
- Use alternative sites to monitor your blood glucose before, or more than two hours after, you eat a meal, take insulin, or exercise.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 84

- **Do not** use blood samples from alternative sites when:

  1. You think your blood glucose is low or is changing rapidly,
  2. You have been diagnosed with hypoglycemic unawareness,
  3. The results from alternative sites do not match the way you feel,
  4. It is within two hours of eating a meal, taking insulin, or exercising, or
  5. You monitor your blood ß-Ketone.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 85

CHAPTER 10

Caring For Your Monitor

Questions? Call Customer Service. See page 87.

Cleaning Your Monitor

Store your monitor in its carrying case.

If the surface of your monitor gets dirty, you may clean it. Use a damp cloth and mild soap.

Healthcare professionals: Acceptable cleaning solutions include 10% Bleach, 70% Alcohol, or 10% Ammonia.

Important:

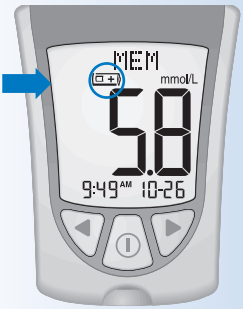
Do not try to clean the electrode port.

Do not pour liquid into the electrode port or buttons.

Do not place your monitor in water or any other bath.

Replacing Your Monitor's Battery

When your monitor needs its batteries replaced, the display window shows one of two things:



This means the battery is low. You may still use your monitor and the results will be accurate. However, the backlight is not useable. It is recommended that you replace the battery at this time.

This means the battery must be replaced. The monitor is not useable. The monitor turns off automatically.

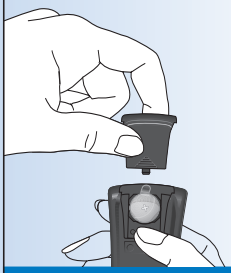
Important:

Do not remove the old battery until you have a new battery to install. It may be necessary to reset the time and date once you install a new battery.

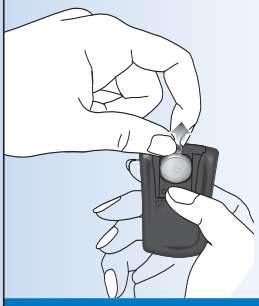
133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 87

How to Replace Your Monitor's Battery

1 Gently push the battery cover in and up with your thumb.



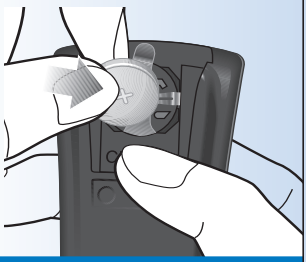
2 Lift the battery cover out of the monitor.



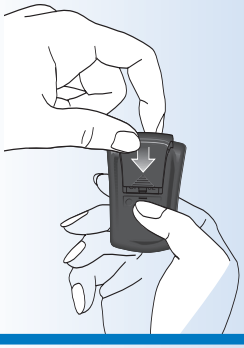
3 Pull on the plastic tab sticking out of the monitor to remove the old battery.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 88

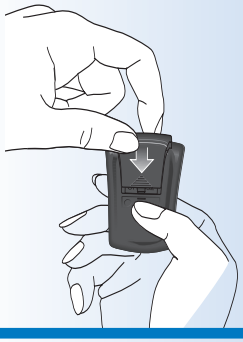
4 Insert a new CR 2032 Lithium (coin cell) battery with the plus sign (+) facing up.



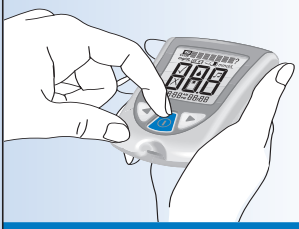
5 Place the notches on the battery cover into the appropriate molded areas.



6 Gently push the battery cover in and down until you hear a click.



133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 89



7 Press and Hold the ⏻ button to turn your monitor on. If your monitor does not turn on, review the battery installation steps and reinstall the battery.

8 Check the date and time on your monitor. You may automatically be prompted to reset the time and date when you first press the mode button to turn your monitor on. (See Chapter 2, Setting Up Your System).

9 Be sure to discard the old battery in compliance with your local government's regulations.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 90

Support & Guarantee

▶ Support

Questions? Call Customer Service.

Abbott Laboratories, MediSense Products is committed to providing you with support. Call us with any questions you may have about your Optium Xceed monitor: In Australia, 1800 801 478, in New Zealand, 0800 106 100.

Outside Australia and New Zealand, please contact your local Abbott Laboratories, MediSense Products office or distributor.

You can also visit us online at www.medisense.com.au or email us at reception.australia@abbott.com.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 91

Guarantee

The MediSense Customer Service team is available to answer any questions you may have about getting the best out of your MediSense monitor. The team is highly experienced at providing advice and troubleshooting problems. Part of the MediSense commitment to customer care is the lifetime warranty on every MediSense monitor. This specifies conditions under which, if your MediSense monitor ever breaks down, MediSense will replace it free of charge. The MediSense Customer Service team can help you with your warranty enquiries. Remember - information and advice about your MediSense monitor is as close as your phone. Call the MediSense Customer Service team: Australia 1800 801 478 or New Zealand 0800 106 100.

133-221 Manual,G3b,Aus 3/17/05 11:15 AM Page 92

References

1. Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

2. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. *Special Topics in Endocrinology and Metabolism* 1982; 4:1–27.

3. Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden DR, Trimble ER, Bell PM. Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management. *Diabetes Care* 1997; 20:1347–52.

4. Harano Y, Kosugi K, Hyosu T, Suzuki M, Hidaka H, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for Type 1 (insulin-dependent) diabetes and their value in the monitoring of diabetes control. *Diabetologia* 1984; 26:343–8.

5. Ubukata E. Diurnal variation of blood ketone bodies in insulin-dependent diabetes mellitus and non-insulin-dependent diabetes mellitus patients: The relationship to serum C-peptide immunoreactivity and free insulin. *Ann Nutr Metab* 1990; 34:333–42.

6. Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. *Diabetes* 1988; 37:1470–77.

7. Hale PJ, Crase J, Nattrass M. Metabolic effects of bicarbonate in the treatment of diabetic ketoacidosis. *Br Med J* 1984; 289; 1035–8.